

§ 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins.

The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may be used as an article or as a component of an article intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(2,6-dimethyl-1,4-phenylene) oxide resins consist of basic resins produced by the oxidative coupling of 2,6-xyleneol such that the finished basic resins meet the specifications and extractives limitations prescribed in paragraph (c) of this section.

(b) *Optional adjuvant substances.* The basic poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic poly(2,6-dimethyl-1,4-phenylene) oxide resins may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations (expressed as percent by weight of finished basic resin)
Diethylamine	Not to exceed 0.16 percent as residual catalyst.
Methyl alcohol	Not to exceed 0.02 percent as residual solvent.
Toluene	Not to exceed 0.2 percent as residual solvent.

(c) *Specifications and extractives limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide basic resins meet the following:

(1) *Specifications.* Intrinsic viscosity is not less than 0.30 deciliter per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference, modified as follows. Copies of the incorporation by reference may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(i) *Solvent:* Chloroform, reagent grade containing 0.01 percent *tert*-butylcatechol.

(ii) *Resin sample:* Powdered resin obtained from production prior to molding or extrusion.

(iii) *Viscometer:* Cannon-Ubbelohde series 25 dilution viscometer (or equivalent).

(iv) *Calculation:* The calculation method used is that described in appendix X.1.3 (ASTM method D1243-79, cited and incorporated by reference in paragraph (c)(1) of this section) with the reduced viscosity determined for three concentration levels (0.4, 0.2, and 0.1 gram per deciliter) and extrapolated to zero concentration for intrinsic viscosity. The following formula is used for determining reduced viscosity:

$$\text{Reduced viscosity in terms of deciliters per gram} = \frac{t - t_o}{t_o \times c}$$

where:

t =Solution efflux time.

t_o =Solvent efflux time.

c =Concentration of solution in terms of grams per deciliter.

(2) *Extractives limitations.* Total resin extracted not to exceed 0.02 weight-percent when extracted with *n*-heptane at 160 °F for 2 hours as determined using 200 milliliters of reagent grade *n*-heptane which has been freshly distilled before use and 25 grams of poly(2,6-dimethyl-1,4-phenylene) oxide resin. The resin as tested is in pellet form having a particle size such that 100 percent of the pellets will pass through a U.S. Standard Sieve No. 6 and 100 percent of the pellets will be held on a U.S. Standard Sieve No. 10.

(d) *Other limitations.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.

(e) *Uses.* The poly(2,6-dimethyl-1,4-phenylene) oxide resins identified in and complying with the limitations in this section may be used as articles or

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components of articles intended for repeated food-contact use or as articles or components of articles intended for single-service food-contact use only under the conditions described in § 176.170(c) of this chapter, table 2, conditions of use H.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984; 63 FR 8852, Feb. 23, 1998]

§ 177.2465 Polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers.

Polymethylmethacrylate/poly(trimethoxysilylpropyl) methacrylate copolymers (CAS Reg. No. 26936-30-1) may be safely used as components of surface primers used in conjunction with silicone polymers intended for repeated use and complying with § 175.300 of this chapter and § 177.2600, in accordance with the following prescribed conditions.

(a) *Identity.* For the purpose of this section, polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers are produced by the polymerization of methylmethacrylate and trimethoxysilylpropylmethacrylate.

(b) *Conditions of use.* (1) The polymethylmethacrylate/poly(trimethoxysilylpropyl)methacrylate copolymers are used at levels not to exceed 6.0 percent by weight of the primer formulation.

(2) The copolymers may be used in food contact applications with all food types under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter.

[59 FR 5948, Feb. 9, 1994]

§ 177.2470 Polyoxymethylene copolymer.

Polyoxymethylene copolymer identified in this section may be safely used as an article or component of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene copolymers are identified as the following: The reaction product of trioxane (cyclic trimer of formaldehyde) and ethylene oxide (CAS Reg. No. 24969-25-3) or the reaction product of trioxane (cyclic

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trimer of formaldehyde) and a maximum of 5 percent by weight of butanediol formal (CAS Reg. No. 25214-85-1). Both copolymers may have certain optional substances added to impart desired technological properties to the copolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene copolymer identified in paragraph (a) of this section may contain optional adjuvant substances required in its production. The quantity of any optional adjuvant substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in parts 170 through 189 of this chapter, and the following:

(1) Stabilizers (total amount of stabilizers not to exceed 2.0 percent and amount of any one stabilizer not to exceed 1.0 percent of polymer by weight)

Calcium ricinoleate.

Cyanoguanidine.

Hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).

Melamine-formaldehyde resin.

2,2'-Methylenebis(4-methyl-6-*tert*-butyl-phenol).

Nylon 6/66, weight ratio 2/3.

Tetrakis [methylene (3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate)] methane.

(2) Lubricant: N,N'-Distearoyl ethylenediamine.

(c) *Specifications.* (1) Polyoxymethylene copolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the copolymer is 15,000 as determined by a method titled "Number Average Molecular Weight," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(d) *Extractive limitations.* (1) Polyoxymethylene copolymer in the finished form in which it is to contact food,